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IN THE SUPREME COURT OF CALIFORNIA

PAUL DOWHAL, Plaintiff and Appellant, v. SMITHKLINE BEECHAM CONSUMER HEALTHCARE et al., Defendants and Respondents.	S109306 Ct.App. 1/5 A094460 San Francisco County Super. Ct. No. 305893

Plaintiff filed this action to challenge the failure of defendants to place health warnings mandated by California's Proposition 65 on products containing nicotine sold over the counter as aids to stop smoking. The trial court granted summary judgment to defendants, ruling that in this setting the requirements of Proposition 65 were impliedly preempted by the federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 301 et seq.). The Court of Appeal reversed; we granted review.

We conclude: (1) Notwithstanding language in the FDCA exempting Proposition 65 from the preemptive effect of the federal act, when the warning mandated by California law directly conflicts with the one that the federal Food and Drug Administration (FDA) requires, the federal requirement prevails; (2) this is a case of direct conflict; and (3) the FDA has authority to prohibit use of the Proposition 65 warning, even though that warning is literally truthful, if the FDA

concludes that it would have the effect of misleading consumers. We therefore reverse the judgment of the Court of Appeal.

I. FACTUAL AND PROCEDURAL BACKGROUND

On November 4, 1986, the voters of this state enacted Proposition 65 as an initiative measure. Proposition 65 added section 25249.6 to the Health and Safety Code: "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause . . . reproductive toxicity without first giving clear and reasonable warning to such individual . . . ." This provision does not apply, however, to "[a]n exposure for which federal law governs warning in a manner that preempts state authority." (Health & Saf. Code, § 25249.10.)

The regulations adopted to implement Health and Safety Code section 25249.6 state that the required warning "must clearly communicate that the chemical in question is known to the state to cause . . . birth defects or other reproductive harm." (Cal. Code Regs., tit. 22, § 12601, subd. (a).) The regulations also describe optional "safe harbor" warnings that are deemed to be clear and reasonable. (*Id.*, § 12601, subd. (b).) One of the "safe harbor" warnings reads: "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." (*Id.*, § 12601, subd. (b)(4)(B).) The warning may be communicated through product labeling, point-of-sale signs, or public advertising. (*Id.*, § 12601, subd. (b)(1)(A)-(C).)

On April 1, 1990, the State of California listed nicotine as a chemical known to cause reproductive toxicity. (Cal. Code Regs., tit. 22, § 12000(c).) This listing was based on the then current determination by the FDA that because of the dangerous consequences of fetal nicotine exposure, nicotine delivery products

should be rated in "Category X" – not for use by pregnant women.[1] Consequently, *to conform to Proposition 65*, defendants' products must carry a warning that "this product contains nicotine, a chemical known to the state of California to cause reproductive harm," or words to that effect.

The FDA, however, has never permitted defendants to use the Proposition 65 warning. The FDA's currently approved warning does not state that nicotine can cause reproductive harm. It requires the product label to state: "If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known." The difference between the two warnings is the focus of this case.

The FDCA prohibits a drug manufacturer from marketing a new drug unless the FDA has approved the drug as both safe and effective for its intended use. (21 U.S.C. § 355.) In addition to scientific and experimental data, a new drug application must include a proposed label. (21 U.S.C. § 355(b)(1)(F).) If the FDA determines that the labeling is false or misleading in any way, the drug is deemed "misbranded," and the FDA will reject the application for approval of the drug. (21 U.S.C. § 352(a).) Once an application has been approved, any change in the labeling requires a supplement to the application and approval by the FDA, either before or after the change. (21 C.F.R. §§ 314.70, 314.71 (2003).)

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[1] In 1992 the FDA reclassified nicotine delivery products, placing them in categories C and D, which permits use by pregnant women with a doctor's prescription.

The issue here is whether California's Proposition 65 requirements are preempted by the FDA regulation, or preserved by the savings clause, section 379r(d)(2), of the Food and Drug Administration Modernization Act of 1997 (Modernization Act) (Pub. L. No. 105-115 (Nov. 21, 1997) 111 Stat. 2296). Section 379r(a) establishes the preemptive effective of federal regulation; it states in part: "[N]o State or political subdivision of a State may establish or continue in effect any requirement -- [¶] . . . . (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter . . . ." The Modernization Act, however, contained a savings clause designed specifically to preserve Proposition 65. It provides: "This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997." (21 U.S.C. § 379r(d)(2).) Proposition 65 is the only state enactment that falls within the savings clause.

Defendants here manufacture, market, and distribute products, such as gum and patches, that are designed to help people quit smoking through nicotine replacement therapy (NRT).[2] Originally, the products were available only by prescription. In 1993, defendants sought FDA approval to sell them over the counter. Defendants' application presented a complex labeling issue because the products contain nicotine, a substance that if taken by a pregnant woman could cause harm to the fetus. On the other hand, the purpose of the products is to help

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[2] Defendants are GlaxoSmithKline Consumer Healthcare, LP (formerly SmithKline Beecham Consumer Healthcare), which markets Nicorette and NicoDerm CQ; McNeil Consumer Products Company and Pharmacia & Upjohn, Inc., which have marketed Nicotrol; Aventis Pharmaceuticals Inc., which is involved in the packaging of NicoDerm CQ; Alza Corporation, which manufactures NicoDerm CQ, and Costco Wholesale Corporation, Lucky Stores, Inc., Rite Aid Corporation, Safeway, Inc., and Walgreen Co., which retail Nicorette, NicoDerm CQ, and/or Nicotrol.

individuals stop smoking, and smoking is even more dangerous to the fetus, because it may deliver more nicotine than the NRT products, and also exposes the smoker to carbon monoxide and other harmful chemicals. As the chairman of the FDA's Nonprescription Drugs Advisory Committee stated: "This is one of the few instances where we have a product that has come before this committee that I would like lots of people to use, that I think we are underusing. . . . [¶] So we want to make sure that we are not introducing barriers that would prevent people from using them, and what is worse, somebody continuing to smoke or not calling their physician and talking with him. . . . [¶] I think, at least as I am interpreting the sense of the committee is that let's be real careful on something we want people to use more of that we don't introduce barriers that would reduce their willingness to use the product." (FDA Nonprescription Drugs Advisory Meeting (Apr. 19, 1996), pp. 169-170.)

Partly in an effort to balance these competing concerns, the products underwent an unusually long approval process. As of 1996, the labels for the original Nicorette, Nicoderm, and Nicotrol prescription products carried a required warning: "Nicotine in any form may cause harm to your unborn baby." (This is the warning required for prescription drugs containing nicotine in 1996.) But when the FDA approved over-the-counter sales in 1996, the FDA advised defendants that their products could carry the following pregnancy warning: "Nicotine can increase your baby's heart rate; . . . if you are pregnant or nursing a baby, seek the advice of a health professional before using this product."[3] Failure

[3] The warnings for the various products differ in some minor respects. No party to this appeal contends the differences are relevant for purposes of this appeal.

to label the products "exactly as requested," the FDA warned producers, "may render the product mislabeled."

In January 1997, defendant McNeil asked the FDA for permission to change the label for its product Nicotrol to add the Proposition 65 "safe harbor" warning: "This product contains nicotine, a chemical known to the State of California to cause birth defects or other reproductive harm." The FDA denied the request, telling McNeil it "[m]ust use the labeling that was approved at the time of . . . approval."

The California Attorney General, however, determined in a letter issued July 10, 1998, that the "increased heart rate" warning did not comply with Proposition 65, because it failed to warn that nicotine can "harm" the fetus, and suggested that nicotine only posed a narrow risk of an increased fetal heart rate "when the true risks appear to be significantly broader and more serious."

In August 1999, after the enactment of the Modernization Act, plaintiff Paul Dowhal, acting on behalf of the public, filed the complaint here. Plaintiff alleged defendants violated Health and Safety Code section 25249.6 because they placed products containing nicotine into the "stream of commerce" without the pregnancy warning required by Proposition 65. Plaintiff also alleged that by failing to provide an adequate warning, defendants committed an unfair business practice in violation of Business and Professions Code section 17200 et seq. He asked for an injunction barring defendants from offering their products for sale in California without providing an adequate Proposition 65 warning.

In November 1999, while this case was pending, the FDA granted permission to Novartis Consumer Health Care, Inc. (Novartis) to sell an NRT product called Habitrol. (Novartis is not a party to this case.) Although Habitrol is identical to some of defendants' products in nicotine content, indication for use, and method of administration, the FDA approved Novartis's warning to

consumers: "Nicotine, whether from smoking or medication, can harm your baby."

When defendant SmithKline learned about the Habitrol pregnancy warning, it asked the FDA whether it should change its warning. The FDA responded that it was "reviewing its position as it relates to the warnings of nicotine products concerning pregnancy and breast feeding." In May 2000, defendants SmithKline and McNeil each wrote to the FDA, again pointing out that Habitrol carried a different pregnancy warning than their products and that they faced litigation over the adequacy of their warning. In June 2000, the FDA responded to SmithKline that while the FDA was reviewing its position on the pregnancy warning, SmithKline should continue to "use the current warning."

On July 11, 2000, counsel for SmithKline wrote to the FDA seeking confirmation about the pregnancy warning that was required. The FDA responded by letter 10 days later, stating that the products "must" carry the pregnancy warning that had been specified when they were approved.

In March 2001, the FDA sent a letter to SmithKline stating that even though Habitrol carried a different warning, the instructions concerning defendants' products remained unchanged: "The agency is currently reviewing its position regarding the pregnancy/nursing warning on [over-the-counter] nicotine replacement products. [¶] . . . As we have stated previously, until the agency's review is complete, all sponsors of [over-the-counter] nicotine replacement products should continue to use the pregnancy/nursing warning that was approved by the agency as part of their [new drug approval]. *Any additional or modified warning may render the product misbranded.*" (Italics added.)

While defendants were working with the FDA in an effort to clarify their obligation to warn, plaintiff moved for summary adjudication. Defendants filed a cross-motion for summary judgment, arguing that federal law preempted any

obligation to warn under Proposition 65. The trial court denied plaintiff's motion, granted defendants' motion, and entered judgment for defendants. Plaintiff appealed.

While this appeal was pending, the FDA responded to a citizen's petition that plaintiff had filed with the agency on August 2, 2000. In a letter to plaintiff mailed August 17, 2001 (hereafter sometimes referred to as the August 17 letter)[4], the FDA reviewed the medical literature, and said it would "grant [plaintiff's] request for a consistent pregnancy warning for all [over-the-counter] NRT drug products that clearly and reasonably communicates all of the known harm and conveys the relative reproductive harm of smoking, use of NRT drug products, and total abstinence from nicotine." The FDA denied plaintiff's request to require a warning on all NRT drug products similar to the "can harm your baby" warning on Habitrol. That warning, the FDA asserted, "overstates what is actually known about nicotine and its effect on the unborn child." It also rejected a proposal to use a label similar to that required for prescription drugs on the ground that the warning to doctors was "not easily translated into consumer friendly language." The FDA agreed that the "can increase your baby's heart rate" warning was insufficient, because it might lead consumers to believe that this was the only possible effect of nicotine. It proposed, instead, that all nicotine replacement

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[4] On October 4, 2001, plaintiff and defendants filed a joint request asking the Court of Appeal to take judicial notice of the August 17 letter. The Court of Appeal exercised its discretion to grant judicial notice, so this letter is now part of the record on appeal. The August 17 letter is attached as an appendix to this opinion.

Because plaintiff's action seeks injunctive relief, an appellate court can take into account events occurring after the trial court judgment. (See *Fisher v. City of Berkeley* (1984) 37 Cal.3d 644, 654, fn. 3 [changes in the law]; *Reserve Insurance Co. v. Pisciotta* (1982) 30 Cal.3d 800, 813 [new facts not in dispute].)

products, including the products at issue and Habitrol, bear the uniform pregnancy warning quoted earlier in this opinion. (*Ante*, at p. 3.) This warning advised pregnant women to consult their health care provider, recommended that they try to stop smoking without using an NRT product, and told them that the medical risks to their child from the product were not fully known.

The Court of Appeal majority here reversed the judgment of the trial court. It concluded that the savings clause in the Modernization Act precluded federal preemption of Proposition 65 warnings, even if there was a direct conflict between those warnings and FDA requirements. The concurring opinion found no conflict between Proposition 65 and the FDA requirements on three grounds: (1) a truthful Proposition 65 label would not conflict with the policy of the FDCA; (2) the informal letters from the FDA to defendants were insufficient to create a preemptive federal policy; and (3) Proposition 65 warnings need not be placed on the package, but could be posted elsewhere where consumers could see them.

We granted defendants' petition for review.

II. DOES THE MODERNIZATION ACT PRECLUDE CONFLICT PREEMPTION?

The supremacy clause of article VI of the United States Constitution grants Congress the power to preempt state law. State law that conflicts with a federal statute is " 'without effect.' " (*Cipollone v. Liggett Group, Inc.* (1992) 505 U.S. 504, 516 (*Cipollone*), quoting *Maryland v. Louisiana* (1981) 451 U.S. 725, 746.) It is equally well established that "[c]onsideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.' " (*Cipollone*, at p. 516.) Thus, " ' "[t]he purpose of Congress is the ultimate touchstone" ' of pre-emption analysis." (*Ibid*.)

The United States Supreme Court has explained that federal preemption arises in three circumstances: "First, Congress can define explicitly the extent to which its enactments pre-empt state law. [Citation.] Pre-emption fundamentally is a question of congressional intent, [citation] and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one. [¶] Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. Such an intent may be inferred from a 'scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,' or where an Act of Congress 'touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.' [Citation.] Although this Court has not hesitated to draw an inference of field pre-emption where it is supported by the federal statutory and regulatory schemes, it has emphasized: 'Where . . . the field which Congress is said to have pre-empted' includes areas that have 'been traditionally occupied by the States,' congressional intent to supersede state laws must be ' "clear and manifest." ' [Citations.] [¶] Finally, state law is pre-empted to the extent that it actually conflicts with federal law. Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements, [citation] or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " (*English v. General Electric Co.* (1990) 496 U.S. 72, 78-79, fn. omitted; see *Crosby v. National Foreign Trade Council* (2000) 530 U.S. 363, 372-373; *Olszewski v. Scripps Health* (2003) 30 Cal.4th 798, 814.)

The first and second forms of preemption are inapplicable here. The savings clause in the Modernization Act demonstrates both that Congress did not

expressly preempt California law, and that it did not occupy the field of labeling of over-the-counter drugs. Thus the issue here concerns the third form of preemption, referred to as "conflict preemption."

Congress has the power to preclude conflict preemption, allowing states to enforce laws even if those laws are in direct conflict with federal law or frustrate the purpose of federal law. (*Geier v. American Honda Motor Co., Inc.* (2000) 529 U.S. 861, 872 [*Geier*].) The Court of Appeal here, relying on the language of the Modernization Act, concluded that Congress had so exercised its power.

The Modernization Act, in 21 United States Code section 379r(a), prohibits states from enacting "any requirement . . . that is different from or in addition to, or that is not identical with, a requirement under this chapter." Section 379r(d)(2) then provides that section 379r does not apply to certain state initiative measures; Proposition 65 comes within this exemption. From this language the Court of Appeal reasoned that California may establish requirements different from, and thus in conflict with, the FDA requirements.

A Proposition 65 requirement, however, may be "different from, in addition to, or . . . not identical" (21 U.S.C. § 379r(a)) to an FDA requirement without actually conflicting with the federal requirement. Here, for example, if the FDA had simply required the warning that "[n]icotine can increase your baby's heart rate," but had not prohibited other warnings, a Proposition 65 warning that nicotine "is known . . . to cause birth defects or other reproductive harm" (Cal. Code Regs., tit. 22, § 12601, subd. (a)) would not conflict with the federal requirement. The product label could simply contain both warnings. Thus, contrary to the Court of Appeal's view, recognizing conflict preemption would not nullify the savings clause of section 379r.

The United States Supreme Court's decision in *Geier, supra,* 529 U.S. 861, established a strong presumption that Congress does not ordinarily intend to bar

conflict preemption. The issue in that case was whether the 1984 version of the Federal Motor Vehicle Safety Standard promulgated by the Department of Transportation relating to airbags preempted a state common law tort action alleging that the defendant manufacturer should have equipped its car with airbags. The federal standard provided for a variety of passive restraints and a gradual phasing-in of airbags. It was based in part on the Transportation Department's fear of a consumer backlash if it were to require airbags on all cars at that time.

The controlling statute in *Geier, supra,* 529 U.S. 861, like the statute in the case here, prohibited states from establishing standards not identical to federal standards. (15 U.S.C. former § 1392(d).) It further provided, however, that "compliance with" a federal safety standard "does not exempt any person from any liability under common law." (15 U.S.C. former § 1397(k).) The United States Supreme Court held that this savings clause removed tort actions from the scope of the express preemption clause, but did not foreclose conflict preemption. (*Geier, supra,* 529 U.S. at p. 869.)

The high court went on to say: "Nothing in the language of the savings clause suggests an intent to save state-law actions that conflict with federal regulations. The words 'compliance' and 'does not exempt' [citation] sound as if they simply bar a special kind of defense, namely, a defense that compliance with a federal standard automatically exempts a defendant from state law whether the Federal Government meant that standard to be an absolute requirement or only a minimum one. [Citation.] It is difficult to understand why Congress would have insisted on a compliance with-federal-regulation precondition to the provision's applicability had it wished the Act to 'save' all state-law tort actions, regardless of their potential threat to the objectives of federal safety standards promulgated under that Act." (*Geier*, *supra*, 529 U.S. at pp. 869-870.)

Geier also gave "some weight" to the Department of Transportation's conclusion that allowing tort suits against manufacturers who had complied with the department's airbag rules would stand as an obstacle to the accomplishment of federal objectives. (*Geier, supra,* 529 U.S. at p. 883.) It explained its deference to the department's conclusion: "Congress has delegated to DOT authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements." (*Ibid.*)

Geier concluded that the savings clause in that case preserved state tort law only when the federal regulation was intended to provide a minimum standard, not when it was intended to establish an absolute standard. Plaintiff here seeks to confine *Geier* by pointing to differences between the savings clause at issue in *Geier* and the savings clause in the Modernization Act. He notes also the difference between preempting a common law tort action, as was involved in *Geier*, and preempting a state regulation. But later cases confirm that *Geier* is not a narrow holding limited to automobile safety standards; instead it established a general rule upholding conflict preemption even if the applicable federal law contains a savings clause. (See *Sprietsma v. Mercury Marine* (2002) 537 U.S. 51, 63; *Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341, 352.) The United States Supreme Court has never interpreted a savings clause so broadly as to permit a state enactment to conflict with a federal regulation scheme.[5]

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[5] *Oxygenated Fuels Ass'n., Inc. v. Davis* (9th Cir. 2003) 331 F.3d 665, held that the Clean Air Act (42 U.S.C. § 7401 et seq.) did not preempt a conflicting California regulation (Cal. Code Regs., tit. 13, § 2262.6 (2003)) prohibiting use of the gasoline additive MTBE. That decision was not based on the savings clause in the federal statute (42 U.S.C. § 7545 (c)(4) (B)), which did not apply to the

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The language of the Modernization Act's savings clause does not express an intention to preclude all conflict preemption. The legislative history suggests an intent to preclude conflict preemption in pursuit of national uniform labeling.[6] In light of that language, history, and the principles established by *Geier, supra,* 529 U.S. 861 and other United States Supreme Court decisions, we conclude that the savings clause of 21 United States Code section 397r(d)(2), does not entirely exclude conflict preemption.

We do not, however, go as far as the United States Attorney General urges in his amicus curiae brief and hold that the savings clause, by nullifying the preemptive effect of 21 United States Code section 397(a), left the law of implied preemption, so far as Proposition 65 is concerned, as if neither were enacted. Such an interpretation would allow the FDA to pursue a goal of national uniformity in warnings, and to further that goal by preempting all Proposition 65 warnings. Section 397r(a) and (d)(2), however, establish that a Proposition 65 warning cannot be preempted solely because it is not identical with the federal requirement. If the FDA's directive here prohibiting nonidentical labels is to be

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California regulation, but on evidence that Congress did not intend to preempt such state regulation.

6 During the floor debate on the Modernization Act, Senator Barbara Boxer stated: "I want to thank Senators Gregg and Jeffords for working with me to ensure that California's proposition 65 will not be preempted by the uniformity provisions of this bill . . . Proposition 65 has successfully reduced toxic contaminants in a number of consumer products sold in California and it has even led the FDA to adopt more stringent standards for some consumer products . . . . So I am very pleased that the FDA reform bill now being debated will exempt California's proposition 65." (Remarks of Sen. Boxer, 143 Cong. Rec. S9811, S9843 (Sept. 24, 1997). "Such statements . . . can provide evidence of Congress' intent." (*Brock v. Pierce County* (1986) 476 U.S. 253, 263.)

sustained, it must be on a basis relevant to consumer health, and not because the Proposition 65 label would frustrate the FDA's policy favoring national uniformity.

III. IS THERE A DIRECT CONFLICT BETWEEN THE WARNING REQUIRED BY PROPOSITION 65 AND THE ORDERS OF THE FDA?

The language required by the FDA's August 17, 2001, letter is not necessarily inconsistent with a Proposition 65 warning to consumers that defendants' products contain nicotine, a chemical known to cause reproductive harm. The apparent conflict arises from the FDA's insistence that defendants must use the warning it has promulgated unless they have data to support a different warning. The FDA has rejected plaintiff's claim that his data justify a different warning, and defendants do not claim to have any additional data. Thus, if a defendant were to add a warning to its label advising that nicotine can cause fetal harm, it would violate the FDA's determination and would risk legal sanctions.

Plaintiff contends, however, that the FDA action is not sufficiently definite and authoritative to create a conflict with state law. Before August 17, 2001, the FDA had regularly sent letters instructing defendants not to add any additional warnings to the FDA-approved warning, and cautioning them that adding such additional warnings might render the product misbranded. Some letters advised the recipient that the matter was still under consideration. But amicus curiae United States Attorney General, on behalf of the FDA, acknowledges: "Before its disposition of Dowhal's citizen petition [by the August 17, 2001, letter], FDA had not issued definitive advice concerning whether use of Dowhal's proposed warning labeling would render Defendants' products misbranded under the

FDCA." The FDA takes the position that its August 17 letter was the first definitive ruling on the subject.

The FDA's August 17 letter specifically rejected plaintiff's proposed "can harm your baby" warning. (Aug. 17, 2001, letter, p. 8.) It did not expressly reject all possible Proposition 65 warnings. It announced, however, that the FDA had developed "a uniform warning that manufacturers . . . will be requested to implement." (*Id.* at p. 5.) Rejecting all earlier warnings, including both the "fetal heart rate" warning used by defendants and the "can harm your baby" warning used on Habitrol, the FDA said that the label should instead tell the buyer to consult her health care provider for advice. Manufacturers were requested to submit a supplement changing their warning to conform to the warning in the August 17 letter. (*Id.* at pp. 7-8.)

Plaintiff argues that the FDA's August 17 letter did not establish a required federal warning, but merely "requested" defendants to submit supplements. But the term "requested" appears to be simply a matter of courtesy; it is apparent from the tenor of the letter that it imposes a duty on defendants. A company cannot use warnings the FDA considers misleading simply because it chooses not to comply with an FDA request to submit the forms required to change its warnings to the one adopted by the FDA.

Plaintiff and his amici curiae point to language in the FDA's August 17 letter stating that "[a]ny other warnings proposed by the sponsor must be supported by data," as showing that defendants are not required to use warnings identical to the FDA warning. But this is standard language that appears, or is implied, in all FDA labeling decisions. A company is always free to change its label, after notifying the FDA, if it has new data showing the former warning was inappropriate. (See 21 C.F.R. § 314.70 (2003).) The possibility that new data may justify a change in the warning does not invalidate the approval of the

existing warning; that warning continues to be binding until the new data emerge and a change is requested.

Plaintiff and his amici curiae point out that the FDA's August 17 letter has not been published in the Federal Register. There is no requirement, however, that it be so published to be effective. Congress was undoubtedly aware that one common means of FDA regulation is to publish rulings through letters to the parties requesting the rulings. When Congress granted preemptive effect to FDA regulation as to all state regulation except Proposition 65 regulation, it probably had in mind regulation through FDA advisory letters.

In *Geier, supra,* 529 U.S. 861, the United States Supreme Court gave preemptive effect to a federal policy expressed in less formal manner than the FDA policy here. Rejecting a contention that formal notice-and-comment rulemaking should be required before an agency's action has preemptive force, the high court found federal policy to be sufficiently definite as to create a conflict when that policy was set out only in comments of the Department of Transportation accompanying its revision of the airbag rules and in statements in the Solicitor General's brief submitted on the agency's behalf. (*Id.* at pp. 883-884.)

Plaintiff here contends that although the FDA has rejected several proposed labels based on Proposition 65, defendants cannot prevail on their motion for summary judgment unless all possible Proposition 65 labels would conflict with the FDA's determination. (See *Dental Amalgam Mfrs. & Distributors v. Stratton* (9th Cir. 1996) 92 F.3d 807, 810; *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby* (9th Cir. 1992) 958 F.2d 941, 943; *People ex rel. Lungren v. Cotter & Co.* (1997) 53 Cal.App.4th 1373, 1393.) The FDA seeks to prohibit any warning not identical to its own, but the absence of identical language is not enough to justify preemption, since the savings clause specifically allows state regulations that are

"different from . . . [or] otherwise not identical" to FDA requirements. (21 U.S.C. § 379r(a)(2).) In this case, however, any warning that conformed in substance to the FDA's warning would not comply with Health and Safety Code section 25249.6 because it would not provide clear and reasonable warning to the consumer that the product contained a chemical "known . . . to cause . . . reproductive toxicity." Thus, the FDA determination has effectively barred all warnings on labels that comply with Proposition 65.

Finally, plaintiff and his amici curiae point out that Proposition 65 warnings need not appear on labels; warnings can also be conveyed through point-of-sale notices or public advertising. (Cal. Code Regs., tit. 22, § 12601.) Because the FDA regulates only product labeling, they contend that a Proposition 65 warning conveyed through other means cannot be preempted.

The FDA's ruling, however, reflects the concern that Proposition 65 warnings on product labels might lead pregnant women to believe that NRT products were as dangerous as smoking, or nearly so, and thus discourage the women from stopping smoking. Warnings through point-of-sale posters or public advertising could have the same effect of frustrating the purpose of the federal policy. Conflict preemption does not require a direct contradiction between state and federal law; the state law is preempted if state law " 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " (*English v. General Electric Co., supra,* 496 U.S. at p. 79.)

We conclude that the FDA's August 17, 2001, letter established a federal policy prohibiting defendants from giving consumers any warning other than the one approved by the FDA in that letter, and that the use of a Proposition 65 warning would conflict with that policy.

IV. CAN THE FDA PROHIBIT DEFENDANTS FROM USING A TRUTHFUL WARNING?

Plaintiff contends that his proposed warning advising pregnant women that defendants' products contain nicotine which "can harm your baby" -- or words to that effect -- is truthful. He argues that the enforcement authority of the FDA is limited to prohibiting "adulterated or misbranded" products (21 U.S.C. § 331(a)), and that a truthful warning cannot render a product "misbranded." He points out that not only California, but also the United States Surgeon General and the Environmental Protection Agency (EPA) list nicotine as a chemical harmful to the fetus. (See Reducing Tobacco Use, A Report of the Surgeon General (2000) at p. 118; 40 C.F.R. § 372.65 (2003) [EPA determination].) Defendants dispute the point, arguing that the evidence is insufficient to show that nicotine can harm the fetus.

The FDA's August 17, 2001, letter sets out its views on the effect of nicotine on the fetus. Because of the FDA's scientific expertise and long administrative experience, these views are entitled to judicial deference. (*Serono Laboratories, Inc. v. Shalala* (D.C. Cir. 1998) 158 F.3d 1313, 1320; see *Geier, supra,* 529 U.S. at p. 883.) But a close reading of that letter shows that the FDA is aware that nicotine may endanger the fetus.

The August 17 letter states: "Although some of the pharmacologic effects of NRT products on the mother and unborn child are known, the full range of compliance or risks to the unborn child are not fully known. . . . NRT drug products have not been tested in pregnant women . . . Extrapolating from the animal data on nicotine exposure and considering the smoking data in humans, the agency believes that chronic nicotine exposure may represent some risk in humans for embryo-fetal lethality, but likely presents little risk for teratogenic or adverse development effects. . . . While smoking has clearly been associated with fetal

harm, the contribution of nicotine has not been clearly delineated. There are numerous other constitutants of cigarette smoke that may be major contributing factors to the harm caused by smoking. There continue to be unanswered questions involving the clinical pharmacology and toxicology of NRT use during pregnancy in humans and additional research should be conducted to answer those questions." (Aug. 17, 2001, letter, p. 4.)

The FDA's August 17 letter recognized that its approved warning to doctors for prescription products containing nicotine states: "It is presumed that [the product] can cause fetal harm when administered to pregnant women." (Aug. 17 letter at p. 3.) But the FDA explains: "This labeling was intended to provide doctors with information to help them make treatment recommendations to their patients. The complexity of the data regarding exposure to nicotine during pregnancy and the relative risks of smoking versus use of NRT products are not easily translated into consumer friendly language on an OTC package." (Aug. 17 letter at pp. 3-4.)

The August 17 letter rejected the proposal that defendants' products use the "can harm your baby" warning approved for Habitrol. It said that this warning "overstates what is known about nicotine and its effect on the unborn child. The words 'can harm' may suggest to consumers that harm will occur in most, if not all, pregnant women who use NRT products. . . . The 'Harm your baby' warning may lead some consumers simply to continue smoking after failed attempts at abstinence because they will be resigned to the belief that use of NRT drug products are just as harmful as smoking." (Aug. 17 letter at p. 5.)

Contrary to defendants' contention, the FDA's August 17, 2001, letter and its summary of the evidence do not show that the FDA considers the evidence insufficient to show that nicotine can harm the fetus. The letter notes both that the effect of nicotine on the fetus is not fully understood, and that it has not been

shown that defendants' products are harmful. But it does not dispute that the nicotine in defendants' products is a potential hazard to the fetus, even though the risks to the unborn child "are not *fully* known." (Aug. 17 letter at p. 8, italics added.) The FDA's objection to labels warning that nicotine "can" harm the baby is not that they are false, but that consumers may give too much weight to the warnings and decide to continue smoking instead of using an NRT product to stop smoking.

But even though it is probably true that the nicotine in defendants' products can cause reproductive harm, the FDA has authority to prohibit truthful statements on a product label if they are "misleading" (21 U.S.C. § 321(n), § 352(a); see *United States v. Watkins* (9th Cir. 2002) 278 F.3d 961, 967), or if they are not stated in "such manner and form, as are necessary for the protection of users." (21 U.S.C. § 352(f).) There are numerous examples involving product descriptions. For example, in *United States v. Ninety-five Barrels of Vinegar* (1924) 265 U.S. 438, the label on the vinegar said it was made from apples. It was, but it was made from dehydrated apples and was different from vinegar made from fresh apples. The United States Supreme Court found the vinegar to be misbranded, observing that deception "may result from the use of statements not technically false or which may be literally true." (*Id.* at p. 444.) In *United States v. An Article of Food, Etc.* (E.D.N.Y. 1974) 377 F.Supp. 746, the district court found the label of Manischewitz's Diet-Thin matzos misleading because they contained the same number of calories as Manischewitz's plain matzos. The opinion observed: "Even a technically accurate description of a food or drug's content may violate 21 U.S.C. § 343 if the description is misleading in other respects." (*Id.* at p. 749.) In *United States v. An Article of Food* (8th Cir. 1973) 482 F.2d 581, the government did "not challenge the factual accuracy of the Nuclomin label; rather it claims the label is misleading to the public because some of the ingredients are

either not needed in human nutrition or are included in such insignificant amounts as to be valueless." (*Id.* at p. 582.) The federal appellate court held that even though the Nuclomin label was technically accurate, it was misleading, and the product was subject to seizure. (*Id.* at p. 584.)

A truthful warning can be misleading or fail to communicate the facts necessary for the protection of users. This court discussed that concern in *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, a product liability action in which the plaintiff claimed that the FDA-approved warning for Halcion, a prescription drug, was inadequate because it failed to warn of certain dangers. Quoting *Finn v. G.D. Searle & Co.* (1984) 35 Cal.3d 691, 701, Justice Mosk's majority opinion noted: "[E]xperience suggest[s] that if every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given." (*Carlin v. Superior Court, supra,* at p. 1115; see Walsh & Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation* (1986) 41 Food Drug Cosm. L. J. 171, 182.) The concurring and dissenting opinion expanded on this problem. It noted that even if scientific evidence supports the existence of a risk, a warning is not necessarily appropriate: "The problems of overwarning are exacerbated if warnings must be given even as to very remote risks . . . ." (*Carlin v. Superior Court, supra*, 13 Cal.4th at p. 1126 (conc. & dis. opn. of Kennard, J.).) "Against the benefits that may be gained by a warning must be balanced the dangers of overwarning and of less meaningful warnings crowding out necessary warnings, the problems of remote risks, and the seriousness of the possible harm to the consumer." (*Id.* at p. 1133.)

The New Jersey Supreme Court in *R.F. v. Abbott Laboratories* (N.J. 2000) 745 A.2d 1174, in holding that an FDA regulation preempted state law on the duty to warn, reasoned that the FDA could prohibit a truthful warning. The FDA label for donated blood specified a test to determine whether the blood was contaminated with HIV, and established a cutoff point requiring rejection of blood scoring above a certain value. The plaintiff suggested that the FDA label should also require retesting of marginal samples that fell within 10 percent of the cutoff point. The FDA rejected this suggestion, and plaintiff unfortunately was infected with donated blood that fell within this 10 percent range. The court rejected plaintiff's challenge to the FDA regulation, relying on FDA findings that (1) there was no scientific evidence that borderline samples were more likely to be false-negative than samples falling well below the borderline, so retesting of borderline samples would not find many cases of contamination; and (2) blood banks would be likely to throw out donations falling in the borderline range instead of incurring the expense of retesting, a consequence that would imperil the nation's blood supply. (See *id.* at p. 1180.)

The New Jersey Supreme Court emphasized that deciding upon a warning may involve balancing of competing interests. (*R.F. v. Abbott Laboratories, supra,* 745 A.2d at p. 1180.) "The FDA's active involvement at every step of the test's development, approval, and use in the field, reflected the risk-utility analysis undertaken by the FDA to address significant public policy considerations. [¶] [T]he FDA's mandate directing Abbot not to provide for retesting of samples near the cutoff . . . remained in force as part of a conscious ongoing risk-benefit analysis by the FDA in managing a public health crisis." (*Id.* at p. 1192.)

Plaintiff here disputes the proposition that the FDA can undertake a risk-utility analysis in formulating an appropriate label. He relies on the United States Supreme Court decisions in *Food and Drug Admin. v. Brown & Williamson*

Tobacco Corp. (2000) 529 U.S. 120 (*Brown & Williamson*) and *Thompson v. Western States Medical Center* (2002) 535 U.S. 357 (*Western States Medical Center*).

Brown & Williamson concerned whether the FDA could classify tobacco as a drug and regulate it accordingly. The majority held that Congress had precluded FDA regulation. One basis for this conclusion was that if the FDA followed its own reasoning and analysis, it would have to conclude that tobacco was unsafe and ban its distribution – an action that would frustrate congressional acts regulating the growing and marketing of tobacco. (*Brown & Williamson, supra,* 529 U.S. at p. 142.)

In response to that argument, the FDA contended that even though tobacco was unsafe and had no therapeutic purpose, the FDA could balance other considerations, such as the risk of creating a black market for cigarettes, and impose something less than an outright ban. The high court disagreed: "Section 352 (j) focuses on the dangers to the consumer from use of the product, not those stemming from the agency's remedial measures. . . . [¶] The FDA, consistent with the FDCA, may clearly regulate many 'dangerous' products without banning them. Indeed, virtually every drug or device poses dangers under certain conditions. What the FDA may not do is conclude that a drug or device cannot be used safely for any therapeutic purpose and yet, at the same time, allow that product to remain on the market." (*Brown & Williamson, supra*, 529 U. S. at pp. 141-142.)

Thereafter, in *Western States Medical Center, supra,* 535 U.S. 357, the United States Supreme Court held that a provision of the Modernization Act prohibiting the advertising of compounded drugs violated the First Amendment to the federal Constitution. The FDA sought to justify the challenged provision on the ground that it was necessary to prevent unnecessary prescription of

compounded drugs. The court described this argument as "paternalistic" (*id.* at p. 375), and said the FDA's "concern amounts to a fear that people would make bad decisions if given truthful information about compounded drugs." (*Id.* at p. 374.) The high court went on to say: "We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." (*Id.* at p. 374, citing *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Counsel, Inc.* (1976) 425 U.S. 748, 769 [state statute barring advertising of prescription drug prices violates First Amendment].)

Both cases cited by plaintiff raise issues distinct from those here. This case does not involve the marketing of an unsafe product as in *Brown & Williamson, supra,* 529 U.S. 120, and unlike *Western States Medical Center, supra,* 535 U.S. 357, it presents no constitutional issues. There is no question but that the FDA has jurisdiction to regulate the labeling of defendants' products, and that its rulings are valid and preemptive as to products sold in every state, subject only to the savings clause in 21 United States Code section 379r(d)(2).

The United States Supreme Court described the reasoning underlying the FDA arguments in *Brown & Williamson, supra,* 529 U.S. 120, and *Western States Medical Center*, *supra,* 535 U.S. 357, as "paternalistic." The same can be said of the FDA's reasoning here. But we do not know of any statute or constitutional provision that precludes the FDA from taking this approach to regulation of nonprescription drugs. In formulating the label for a product to be marketed – as distinguished from a decision whether or not to permit the product to be marketed – the FDA must take into account the effect of proposed labels on the consumer. Whether a label is potentially misleading or incomprehensible is essentially a judgment of how the consumer will respond to the language of the label. As we

have noted, a truthful warning of an uncertain or remote danger may mislead the consumer into misjudging the dangers stemming from use of the product, and consequently making a medically unwise decision. The authority of the FDA, we conclude, extends to barring warnings that are misleading in this fashion.

Although there is reason to believe that nicotine can cause reproductive harm, plaintiff has offered no qualitative assessment of this risk. The mere existence of the risk, however, is not necessarily enough to justify a warning; the risk of harm may be so remote that it is outweighed by the greater risk that a warning will scare consumers into foregoing use of a product that in most cases will be to their benefit. The FDA has so determined in this case, and we find no basis to question the FDA's expert determination.

The United States Attorney General, as amicus curiae for defendants, goes further and argues that every FDA labeling decision involves balancing all relevant considerations relating to the precise wording of the label, and that consequently any nonidentical state warning would constitute misbranding. That argument would nullify the savings clause in the Modernization Act, which plainly permits Proposition 65 warnings that differ from the FDA warnings. As defendants point out, this is an unusual case; in most cases FDA warnings and Proposition 65 warnings would serve the same purpose – informing the consumer of the risks involved in use of the product – and differences in wording would not call for federal preemption. Here, however, the FDA warning serves a nuanced goal – to inform pregnant women of the risks of NRT products, but in a way that will not lead some women, overly concerned about those risks, to continue smoking. This creates a conflict with the state's more single-minded goal of informing the consumer of the risks. That policy conflict justifies federal preemption here.

DISPOSITION

The judgment of the Court of Appeal is reversed.

KENNARD, ACTING C. J.

WE CONCUR:

WERDEGAR, J.
CHIN, J.
BROWN, J.
MORENO, J.
SCOTLAND, J.*
SEPULVEDA, J.**

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* Presiding Justice of the Court of Appeal, Third Appellate District, assigned by the Acting Chief Justice pursuant to article VI, section 6 of the California Constitution.

** Associate Justice of the Court of Appeal, First Appellate District, Division Four, assigned by the Acting Chief Justice pursuant to article VI, section 6 of the California Constitution.

See last page for addresses and telephone numbers for counsel who argued in Supreme Court.

Name of Opinion Dowhal v. Smithkline Beecham Healthcare

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